

Kathleen & Stephen Unger

27 Sea Colony Drive • Santa Monica, CA 90405 • Tel: (310) 392-9400 Fax: (310) 392-8700

May 26, 1999

8707 '99 JUN -2 10:35

To: Food and Drug Administration

Re: Docket No. 98N-1265

I would like you to please amend the FDA's proposed regulations entitled "Memorandum of Understanding" ("MOU") published on January 21, 1999 regarding compounding pharmacies.

My overall concern focuses on near-term and prospective limitations on my and all other healthcare consumers' options. In its present form, the MOU as well as the Compounding Section 503A of the Modernization Act severely restricts (and can limit in the future) my rights as an individual to obtain healthcare services and products from the provider of my choice.

I am deeply alarmed by the following specific problems raised by the MOU:

- The MOU reduces to 5% the number of prescriptions that a compounding pharmacy can mail out of state.
- The FDA will take control over compounding pharmacies, which control in my case is currently exercised by the California Board of Pharmacy. That concerns me because (1) I believe that state agencies are more in tune with the needs of their constituent healthcare consumers and providers; and (2) I fear that the FDA will eventually require the application of standards and criteria (i.e., testing and documentation) that are wholly inappropriate to individually-compounded, custom-made medications ordered by our physicians.

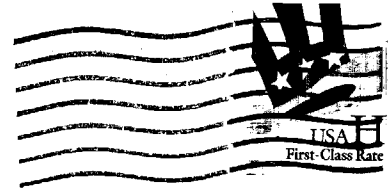
The compounding pharmacies that I know and use both test and use the highest quality materials (which require approved in the first place!) and procedures. I cannot imagine why the FDA is proposing these regulations. Assuming that there are a few problems that have come to the FDA's attention, it seems to me that the MOU can be amended in a limited, surgical fashion to deal with them – rather than abridging our rights on a wholesale basis.

Thank you for your consideration of my concerns.



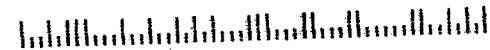
98N-1265

C 3015



Dockets Management Branch (HFA-305)
Food & Drug Administration
5630 Fishers Lane, Room 1061

Rockville
22823743303



UNGER

10877 Wilshire Boulevard Suite 1802 Los Angeles, CA 90024